REMARKS

In response to the Office Action mailed August 19, 2008, Applicants have amended claims 1, 2, 12, and 13. Claim 11 has been canceled and no new claims have been added. It is urged that support for all the above amendments may be found throughout the specification as originally filed, for example on page 3, lines 24-25. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1, 2, 12, and 13 are under examination in the application. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Priority

Applicants thank the Examiner for acknowledging priority to claims 11-13 to the foreign applications AU 2003905551, filed October 10, 2003 and AU 20033906658, filed December, 1, 2003. However, Applicants respectfully note that the subject matter of claims 1, 2, and 11-13 are entitled to claim the benefit of both prior filed applications, and thus, the instant application should properly be accorded a filing date of October 10, 2003.

Specification

The Examiner requests that Applicants review the application for spelling errors, the use of trademarks, embedded hyperlinks and/or other forms of browser executable code. Applicants respectfully note that the Examiner has not pointed out any specific or general errors in the specification. Applicants have searched for and corrected any noticible errors in the as-filed specification. The corrections can be found in the "Amendments to the Specification" section of this response. Applicants respectfully request that the Examiner specifically point out any additional errors for correction. No new matter was added by way of these amendments.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 11-13 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the examiner alleges that claim 12 is indefinite in the recitation of "deimmunized antibody" and that claims 11-13 are indefinite in the recitation of "or otherwise associating with HAS."

Applicants respectfully traverse these bases of rejection and submit that the present claims are both clear and definite and that one having ordinary skill in the art would recognize the metes and bounds of the instant claims.

The Examiner contends that the phrase "deimmunized antibody" in claim 12 is indefinite because it is unclear how a "humanized antibody" is distinct from a "deimmunized antibody" as recited in claims 12. Applicants respectfully disagree and submit that the metes and bounds of claim 12 are clear and definite. Applicants submit that "humanized antibodies" or "chimeric antibodies" are a type of monoclonal antibody that has been synthesized using recombinant DNA technology to circumvent the clinical problem of immune response to foreign antigens. For example, the standard procedure for producing monoclonal antibodies yields mouse antibodies, and although mouse antibodies are very similar to human antibodies, there are polypeptide sequence differences. Thus, the human immune system will recognize a mouse antibody as foreign, and rapidly remove it from circulation; causing systemic inflammation.

Further, humanized antibodies are produced by merging the DNA that encodes the binding portion of a monoclonal mouse antibody with DNA from structural framework of human antibodies. The skilled artisan then uses mammalian cell culture to express this DNA and produces chimeric mouse/human antibodies that have reduced immunogenicity in humans.

Thus, Applicants submit that the as-filed specification in combination with the art-accepted definitions described above indicate that the term "deimmunized antibodies" includes within its scope, "humanized antibodies." For example, the as-filed specification on page 26, lines 26-30, defines "deimmunized" as removing the immunogenicity of an antibody with respect to a target organism, but does not limit the term "deimmunized" to humans or any other organism. For example, an antibody may be "deimmunized" with respect to a bovine and

used for the treatment of a bovine; however, the antibody would remain immunogenic with regard to humans.

Applicants submit that the term "humanized" refers to deimmunizing an antibody with regard to humans as the target organism. Thus, the terms "deimmunized" and "humanized" are interchangeable with respect to therapeutics or diagnostics for human treatment. In contrast, the terms are not interchangeable when referring to the treatment of other organisms. For example, on page 27, lines 9-13, of the as-filed specification refers to the treatment of human (at line 10) and in this instance, the terms "deimmunized" and "humanized" are interchangeable.

Accordingly, one having ordinary skill in the art would understand the metes and bounds of the term "deimmunized" are clear and definite. Nonetheless, Applicants, without acquiescing to any rejection and solely in a good faith effort to expedite prosecution, have amended claim 12 to no longer recite the term "deimmunized." Thus, this rejection has been rendered moot and may be properly withdrawn.

The Examiner further alleges that the phrase "or otherwise associating with HAS" in claims 11-13, because the as-filed specification does not provide only provides antibody binding to HAS. Applicants, without acquiescing to any rejection and solely in a good faith effort to expedite prosecution, have canceled claim 11, and thus, the claims no longer recite the phrase "or otherwise associating with HAS." Accordingly, this rejection has been rendered moot and may be properly withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1, 2, and 11-13 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for allegedly claiming subject matter which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner contends that the as-filed specification fails to provide written description support for "interacting molecules" of claims 11-13 and "conservative amino acid substitutions" of claims 1, 2, and 11-13. Applicants note that claim 11 has been canceled, and thus, these bases of rejection are moot with regard to claim 11.

Applicants, without acquiescing to any rejection and solely in a good faith effort to expedite prosecution, have amended claim 1 to no longer recite "conservative amino acid substitutions". Further Applicants have amended claims 12 and 13 to no longer recite "interactive molecules" and instead recite an antibody. Accordingly, these bases for rejection have been rendered moot and may be properly withdrawn.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 2, and 11-13 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Briskin et al. (U.S. Patent Application Publication No. 2002/0151026). Specifically, the Examiner contends that Briskin et al. teaches an isolated or recombinant nucleic acid, which encodes a mammalian HAS and antibodies that bind to the amino acid residues encoded by polynucleotide positions 1577-1600. The Examiner further alleges that the phrase "one or more conservative amino acid substitutions" in claim 1, does not limit the antibody binding to SEQ ID NO: 25.

Applicants respectfully traverse this basis for rejection and submit that the Briskin et al. reference fails to anticipate the presently claimed invention, because it does not teach each and every limitation of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As noted above, in response to the written description rejection, claim 1 has been amended to remove the phrase "one or more conservative amino acid substitutions." Thus, presently amended claim 1 is directed to an isolated antibody which reduces the level of hyaluronan synthase (HAS) activity wherein said antibody specifically targets SEQ ID NO: 25 within an HAS. Briskin et al. fails to teach, either inherently or explicitly, an antibody that binds to SEQ ID NO: 25, and thus, does not anticipate the presently claimed invention. Reconsideration and withdrawal of this basis for rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1,2, and 11-13 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Briskin et al., in view of Falkenberg et al (*J. Clin. Chem. Clin. Biochem.* 1984, 22:867-883) and Owens et al. (*Journal of Immunological Methods*, 1994, 168:149-165). Specifically, the Examiner contends that while Briskin et al., does not teach a monoclonal, polyclonal, or humanized antibody, it would have been obvious to one of skill in the art at the time of the invention to generate humanized antibodies as taught by Owens et al. The Examiner further contends that it would have been obvious to produce monoclonal and polyclonal antibodies in view of Falkenberg et al.

Applicants traverse this basis of rejection and respectfully submit that the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention because the references do not teach or suggest each and every element of the claims. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, the Action fails to provide a sufficient basis for one having ordinary skill in the art to predictably arrive at the presently claimed invention with any reasonable expectation of success, and thus, the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention.

Applicants submit that the Briskin et al. reference fails to teach or suggest an isolated antibody which reduces the level of hyaluronan synthase (HAS) activity, wherein said antibody specifically targets SEQ ID NO: 25 within an HAS. Moreover, the Owens et al. and Falkenberg et al. references are completely silent with regard to HAS antibodies, let alone a HAS antibody that target SEQ ID NO: 25. At a minimum, it must be demonstrated that the cited references provide a sufficient basis to predictably arrive at the presently claimed invention, and even assuming, *arguendo,* that the cited references teach each claim feature, the Examiner must provide an explicit, apparent reason to combine these features in the fashion claimed by the Applicant with a reasonable expectation of success. *See KSR v. Teleflex, Inc.,* No. 04-1350 at 4, 14 (U.S. Apr. 30, 2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art"). In the instant

case, the Examiner has not provided any rationale to support the why one having ordinary skill in the art would seek to generate monoclonal, polyclonal, or humanized antibodies against any specific amino acid sequence in HAS, let alone in an amino acid sequence represented by SEQ ID NO: 25, as claimed.

Thus, Applicants respectfully submit that this Action fails to support a *prima facie* case of obviousness against the presently claimed invention. Furthermore, in view of the references cited by the Examiner and the level and knowledge in the art, the ordinary skilled artisan would fail to predictably derive the presently claimed antibodies with any expectation of success, as is required under *KSR v. Teleflex, Inc.* Accordingly, reconsideration and withdrawal of this basis of rejection is respectfully requested.

Applicants note that the Examiner correctly acknowledges that Briskin et al. does not teach monoclonal, polyclonal or humanized antibodies, but incorrectly alleges that Briskin et al. does teach a monoclonal antibody that binds to HAS of the present invention (see Action, page 9, second para.).

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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